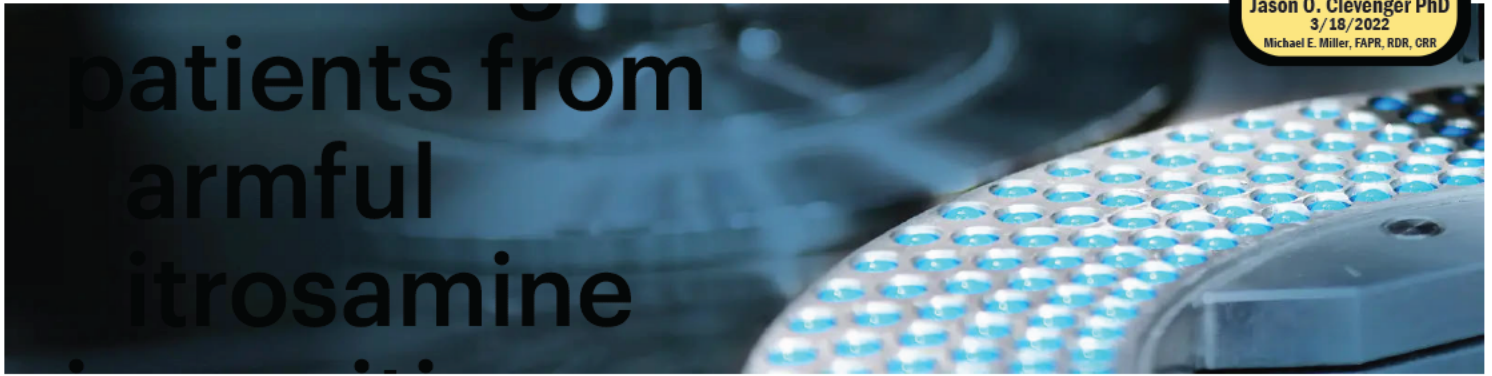


# **EXHIBIT E**

(/)

EXHIBIT  
8

Jason O. Clevenger PhD  
3/18/2022  
Michael E. Miller, FAPR, RDR, ORR



USP (/) / Our Work / Chemical Medicines (/chemical-medicines)

## Nitrosamine impurities

To protect patients and strengthen the global medicines supply chain, USP is providing tools and solutions to analyze and monitor emerging impurities in the drug supply.

Starting in 2018 the presence of nitrosamine impurities was identified in some angiotensin II receptor blocker (ARBs) used to treat high blood pressure and heart failure. Subsequently, nitrosamines impurities have been found in additional drug products, leading to a major effort by regulators and industry to reduce or eliminate their presence in the drug supply.

Companies are responsible for understanding their manufacturing processes, which includes identifying and preventing the presence of unacceptable impurities. This involves developing new predictive approaches, along with using suitable methods to detect and control these impurities as well as others that may arise when making changes to manufacturing processes.

USP is supporting manufacturers and regulators with tools and solutions for testing, assessing risk and understanding potential sources related to nitrosamine impurities.

For additional information or questions about USP's efforts related to nitrosamine

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# Now available: Eight new Nitrosamine Impurities

Discover the value beyond the vial

Standards | Process | Service

Learn more (<https://go.usp.org/nitrosamines-impurities>)



## Genotoxic impurities webinar

Ed Gump, Ph.D., Vice President, USP Small Molecules

Pharmaceutical Technology Editor Series Webcast

"Genotoxic Impurities and Drug Quality--Lessons from the Nitrosamine Contamination Crisis" By clicking the Accept button, you agree to us doing so.

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# New GC 1469 Nitrosamine Impurities – PF46

New GC 1469 Nitrosamines Impurities is now LIVE! ([https://lnkd.in/g\\_aZXr4](https://lnkd.in/g_aZXr4))

To protect patients from adverse effects of nitrosamines as impurities, USP has developed a new general chapter to provide information useful for ensuring the appropriate control of nitrosamine impurities in drug substances and drug products.

GC 1469 will be official on December 1, 2021



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Access PF now (<https://online.usppf.com/usppf>)



## USP proposes analytical methods for drug makers to detect nitrosamine impurities

Read the article (<https://pink.pharmaintelligence.informa.com/PS142872/USP-Proposes-An>)

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USP's Chief Science Officer, Jaap Venema, and Regulatory Science Affairs Director, Kristi Muldoon Jacobs, discuss genotoxic impurities with *Pharmaceutical Technology*.

Read article (<https://www.pharmtech.com/contamination-drives-more-concerted-approach>)

## Building our knowledge about impurities

Learn more ([//chemical-medicines/nitrosamine-impurities/scientific-expertise](https://www.usp.org/chemical-medicines/nitrosamine-impurities/scientific-expertise))

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## Also of Interest

Croscarmellose Sodium (<https://www.usp.org/harmonization-standards/pdg/excipients/croscarmellose-sodium>)

Scientific expertise (<https://www.usp.org/chemical-medicines/nitrosamine-impurities/scientific-expertise>)

Safeguarding patients from nitrosamine impurities... (<https://www.usp.org/our-science/nitrosamine-impurities>)



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